

EFFICACY REVIEW

DATE: 12/4/2008

EPA REG. NUMBER: EPA Reg. No. 239-2685, Bifenthrin Liquid Concentrate

DP BARCODE: D355436

CHEMICAL NO.: 128825

REGISTRANT: The Ortho Business group

GLP: No

CHEMICAL: Bifenthrin 0.3% Liquid Concentrate

PURPOSE: Provide efficacy data to support label claim for fire ant mound control

MRID: 47456401. R. Soufi 2208. Evaluation of the Efficacy of 0.3% Bifenthrin Liquid Concentrate (EPA Reg. No. 239-2685) as a mound treatment for Red Imported Fire Ants; Sponsor- The Scotts Company, Marysville, OH; Performing Laboratories W.C. Mixson and Associates, Apopka, FL and Scotts Company, Apopka, FL;

TEAM REVIEWER: BeWanda Alexander

EFFICACY REVIEWER: Joanne S. Edwards, M.S., Entomologist

Joanne S. Edwards
12/4/08

BACKGROUND:

In letter dated November 13, 2008, Scotts Company submitted a response to the 9/30/08 efficacy review under D355436.

DATA REVIEW:

Excerpted from last review:

"There were three separate field studies conducted. The sites were in Apopka, FL, Thompson, GA, and Cleveland, TX. Reported mound sizes ranged from 10 to 14 inches in diameter. At each site there were four replicates, with each replicate consisting of ten mounds. The report did not say what the four replicates were. Since there was a control group (one gallon of water applied to mound), it may be that three of the replicates consisted of treatment with the product and one replicate was the control, however it is not stated in the report. Mounds were marked with wire surveyor's flags. Evaluation intervals were 5, 15, 30 and 60 minutes, 14 days (at Apopka site only) and 30 days.

Details of the study design excerpted from MRID 47456401:

“Formulation: 0.30% bifenthrin

Type: Mound drench using a hose-end ready-to-spray applicator

Target Insect(s): Red Imported Fire Ant (*Solenopsis invicta*)

Application Information

Timing: Once @ day zero

Rate: One gallon of diluted product was applied to each mound at 1.5 ounces of 0.3% bifenthrin per mound.

Experimental Design: Randomized Complete Block Design

Number of Replicates: Four replicates per treatment.

Each replicate consisted of 10 active mounds.

Experimental Procedure:

Each treatment consisted of four replicates with ten mounds per replicate. Insecticide applications were made to each mound and a 2 foot radius around the mound. Each mound was disturbed when checking for activity. Mounds were considered active if ants were observed walking in a normal manner. Mounds were considered inactive when no ants were capable of moving coherently. A mound was considered dead when at least 95% of the ants were dead.”

Reported Results:

The study author reported that at all sites, 95% of the mounds were realized within fifteen minutes.

Excerpted from MRID 47456401:

“Apopka, FL Speed/Residual Test

Bifenthrin mound drenches began to control Red Imported Fire Ants almost immediately. By 15 minutes, the treatment controlled Red Imported Fire Ant mounds at least 95%. At 30 days after treatment, 1.5 oz/mound Bug B Gon Max controlled fire ant mounds 95% compared to the untreated. Some new mounds were observed, but only 0.5 new mounds/plot were observed within a 10 ft radius of the mounds treated with 1.5 oz Bug B Gon Max/mound.

Thomson, GA Speed/Residual Test

Bifenthrin mound drenches began to control Red Imported Fire Ants almost immediately. By 15 minutes, Bug B Gon Max exhibited 100% control of Red Imported Fire Ant mounds. At 30 days after treatment, Bug B Gon Max controlled fire ant mounds 95% compared to the untreated. Some new mounds were observed, but only 0.5 new mounds/plot were observed within a 10 ft radius of the mounds.

Cleveland, TX Speed/Residual Test

As in the two previous two locations, 0.3% bifenthrin began to quickly work on the mounds. By the 15 minute evaluation, 95% control of the treated mounds was realized. By 30 days after application, all treated mounds were controlled 100% with no mound relocation evident within the required 10 foot radius of any treated mound. One mound relocated from a water-treated plot.”

There were no raw data contained in the report to confirm the numerical finding that 95% of the mounds were dead within fifteen minutes. The mounds were not excavated. The only study design detail on how observations were performed was “mound was disturbed”. Since the mounds were not excavated, there is no way to confirm that the mound *i.e.*, workers, brood, and queen, were dead in fifteen minutes. It could be that just the foraging ants were killed.

Issues With Study:

- Numerical basis statements “95% controlled and “100% controlled” not provided.
- Raw data not included.
- No details on controls.
- Application methodology was different than label directions (apply 30 seconds to mound and adjacent area vs. 1.5 ounces/one gallon of water)
- Details on level of pretreatment mound activity of the treatment/control mounds not provided.
- Details on how a mound was determined to be an active mound lacking.
- Mounds not excavated, *e.g.*, observations on mortality of ants, brood and queen in the mound after fifteen minutes not provided.”

Scotts November 13, 2009 Response:

Scotts clarified the experimental design and provided additional information:

- In each study there were four replicates (each replicate consisting of ten mounds) for the treatment group, and four replicates (each replicate consisting of ten mounds) for the control group.
- One gallon of water was applied to the mound and surrounding two foot radius for the control group
- 1.5 ounces of product in one gallon of water was applied to the mound and surrounding two foot radius for the treatment group.
- Calculations demonstrate the application rate in the field testing is equivalent to the proposed label directions for use to apply to mound and surrounding two foot radius for a period of thirty seconds using a hose-end sprayer (see page 4 of letter).
- Mounds were not characterized for level of fire ant activity. If one ant appeared at surface after prodding of mound, then mound was considered to be an active.
- Mounds were not excavated.
- Synopsis of study findings for the thirty day count period:
Apoka, Florida: Control- 7/40 mounds dead; treated group- 40/40 mounds dead; no new mounds
Thompson, GA: Control- 0/40 mounds dead; treated group- 40/40 mounds dead; 2 new mounds
Cleveland, TX: Control- 0/40 mounds dead; treated group- 40/40 mounds dead; no new mounds

The additional data are deemed sufficient to support a claim for control for fire ant mounds. This information should be included in the MRID.

RECOMMENDATIONS:

Based on the additional information provided, there is no objection to a claim for fire ant mound control.

The submitted data do not support a "quick kill" claim, since mounds were not excavated to observe for live/dead fire ants, brood or queen. It is recommended the company provide a protocol for a study design prior to conducting a study to support a "quick kill" claim (e.g., kills the mound in 15 minutes).

The registrant needs to clarify on page 4 of their letter that the product was applied for 30

seconds to the mound **and surrounding 2-ft area**.

The registrant should be advised that in future studies, the level of fire ant activity in a mound should be better characterized (e.g., use USDA mound population index vs. "mound active if one fire ant seen").

LABEL RECOMMENDATIONS:

Revise "For best results, avoid disturbing treated mounds by keeping people and pets off treated area until spray has dried." "Keep people and pets off treated area until spray has dried."

Revise "[Just] Apply for 30 seconds [directly to mound]" to read "[Just] Apply for 30 seconds [directly to mound] and surrounding 2 foot radius."

Delete the claims below:

- Complete Mound Kill in [15/30/60/90] Minutes
- Kills [Entire Mound in [15/30/60/90] Minutes
- Kills the Queen & [Entire] Mound [in Just 15/30/60/90] Minutes

Defer to PM regarding the phrase "Gentle shower won't disturb the mound", as the term "Gentle" could constitute an implied safety claim. If this term is allowed, then the phrase "won't disturb mound" will need to be removed, since no data were provided to demonstrate that fire ants will not be disturbed when the product is applied.

Defer to PM regarding claims (Mound soaking formula penetrates the entire colony; Mound Penetrating/Soaking Formula and Deep Penetrating Formula). These claims may appear on other labels for liquid products that have claims for fire ant mound control.

Defer to PM: The statement "For best results and a healthy environment, please follow instructions..." (implied safety claim)